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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,227	08/06/2001	Abdul Rasoul Salman	417/9-1553b	8969

7590 12/22/2004

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EXAMINER	
GOLLAMUDI, SHARMILA S	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 12/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/923,227	SALMAN, ABDUL RASOUL	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments/Remarks and Rule 132 Declaration filed September 8, 2003 is acknowledged. Claims **10-14** are pending in this application. Claims 1-9 stand cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recite specific weight percent for specific components and combinations of components that do not have support in the specification at the time the invention was filed.

Claim 10 recites specific weight percents of specific components that do not have support in the specification. For instance, applicant claims an antiseptic selected from glycerin, camphor, alcohol, or zinc sulphate in the amount of 0.1-2 grams per liter. However, page 3 of the instant specification only provides support for glycerin in the amount of 5-50 grams per liter, 0.1-3 grams per liter of zinc sulphate and not 0.1-2 grams per liter, alcohol in the amount of 0.5-3 ml per liter, etc. Applicant claims n-acetyl cystine in the amount of 0.1-3 grams per liter, however the instant specification only provides support for the lower limit 0.1 but not 3 grams per liter.

The examiner has not listed all the instances of new ranges cited by applicant since there are numerous instances of such new matter.

Claim 11 recites camphor in the amount of 0.1-3 grams per liter, however applicant only has support for 0.01-0.1 grams per liter.

Claim 12 recites camphor in the amount of 0.25 grams, however applicant only has support for 0.025 grams. Note Table 1 of instant specification.

Claim 14 recites an antiseptic selected from glycerin, camphor, alcohol, or zinc sulphate in the amount of 0.1-2 grams per liter. However, page 3 of the instant specification only provides support for glycerin in the amount of 5-50 grams per liter, 0.1-3 grams per liter of zinc sulphate and not 0.1-2 grams per liter, alcohol in the amount of 0.5-3 ml per liter, etc. The examiner has not listed all the instances of new ranges cited by applicant since there are numerous instances of such new matter.

The examiner has noted the pages and original claims which applicant's claims supports the new ranges, however this assertion is incorrect.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites "methyl salicylate at from 0.1 to 2 ml per liter and combinations thereof' which is unclear what the combinations thereof intend to encompass.

Further, claim 10 recites "consisting essentially of" language and claim 13 recites "further comprising peppermint oil, thymol,...", which is indefinite since it is unclear what the instant claim language is excluding. The components recited in claim 13 are clearly active ingredients that would materially affect the basic composition of claim 10. Further, clarification is requested.

Claim 11 recites "at least 0.1 to 3 g/liter camphor between 0.1 and 3 grams per liter" which is vague and indefinite.

Claim 12 recites "0.03 grams methyl" which is indefinite since it is unclear what applicant intends to claim.

Claim 14 recites "methyl salicylate at from 0.1 to 2 ml per liter and combinations thereof" which is unclear what the combinations thereof intend to encompass.

Claims 10, 12, and 14 recite "n-acetyl l.cystine" which is not a known compound. It is unclear if applicant intends to claim "n-acetyl-L-cysteine".

Claim Objections

Claim 13 is objected to because of the following informalities: Applicant has misspelled the word eucalyptus. Appropriate correction is required.

Response to Amendment

The Rule 132 under 37 CFR 1.132 filed 9/8/03 is insufficient to overcome the obviousness rejections as set forth in the last Office action because:

Firstly, the applicant has stated that the composition of Sinus Magic, the inventive composition, is in accordance to the claims. However, the applicant has not disclosed the formulation of Sinus Magic since the claims provide for various combinations of components in

various weight percents. Therefore, the scope of the claims allow for numerous possible compositions with various components and concentrations whereas Sinus Magic is a *specific* formulation. Thus, a proper comparison cannot be made.

Secondly, applicant has not provided unexpected data. The examiner points that the results are in fact expected. For instance, the results teach that Sinus Magic relieves pain in the nose, this is expected by the use of an analgesic since it is apparent in the art that analgesics relieve pain. The prior art teaches the individual components in the composition produce applicant's results.

Lastly, applicant has provided an Applicant has not provided a comparison of unexpected results in direct comparison with the closest prior art. Applicant has compared two examples of the prior art compositions but has not compared the prior art's composition with the instant inventive composition.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10-11 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fust (6,344,210) in view of Bryce-Smith (5,622,724).

Fust teaches a composition for freshening nostrils and sinus cavities that include a saline solution, a flavoring agent, a preservative, an antiseptic and/or an antimicrobial, a counter-irritant, and an alcohol. The composition provides clean and healthy nasal passages. The composition also contains zinc. Fust teaches zinc ions are known in the art as powerful and natural anti-rhinoviral agents, immune aids, anti-inflammatory agents, etc. See column 4, lines 20-34. The aromatic masking agents that are taught are peppermint oil, spearmint oil, eucalyptol, methyl salicylate, etc. see column 4, lines 5-10. The basic composition contains water (carrier), 0.1-2% sodium chloride, 0.1-9% alcohol (antiseptic), 0.1-3% glycerin (moisturizing agent), 0.1-5% aromatic component, and 0.001-5% zinc chloride. Specifically, the composition contains 0.65% sodium chloride, 0.02% methyl salicylate (analgesic), 0.015% menthol, 0.07% alcohol (antiseptic), glycerin (moisturizing agent), and zinc chloride. See example 1. The composition is provided in a atomizer spray bottle. See column 4, lines 45-57.

Fust does not specifically teach the use of zinc sulfate.

Bryce-Smith teaches a zinc sulfate nasal spray for treating the common cold. Bryce-Smith teaches the use of zinc and its compounds have been known to possess therapeutic function such as wound healing and astringent functions. Zinc chloride is utilized for foul-smelling wounds and zinc sulphate is utilized for wound healing purposes. See column 1, lines 19-25. Zinc chloride or zinc sulphate may be utilized but Bryce-Smith notes particularly effective results with zinc sulphate. See column 4, lines 54-56. The reference teaches the base solution may be saline, aqueous glycerol, or a mixture of both (col. 5, lines 6-14). Further, Bryce-Smith teaches a preferred solution containing 0.1% menthol, camphor 3% ethanol (antiseptic) and zinc in the amount of 0.01-1%. Camphor is utilized to allow the patient to be

"aware of the solution/" since zinc is unnoticeable. See column 5, lines 38-52. Lastly, Bryce-Smith suggests combining the zinc solution with other medications such as decongestants, antimicrobials, or antihistamines (col. 5, lines 28-45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Fust et al and Bryce-Smith and substitute Fust's zinc chloride with instant zinc sulfate. One would have been motivated to do so since Bryce-Smith teaches the use of zinc, particularly zinc sulphate and zinc chloride, is conventionally utilized in nasal compositions and known in the art for its wound healing and astringent properties, however Bryce-Smith teaches zinc sulphate is particularly effective. Therefore, one would have been motivated to utilize zinc sulphate in Fust's composition rather than zinc chloride for its advantages as taught by Bryce-Smith.

*Note that certain components have dual functions. For instance, the claims require a moisturizing agent and an antiseptic wherein the prior art's glycerol satisfies both since the claims recite glycerol in a Markush group for both an antiseptic and moisturizing agent. Also, zinc sulphate reads on a mucolytic agent and NSAID since the claims recite zinc sulphate in a Markush group for both an a mucolytic agent and an NSAID.

Claims 10-11 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fust (6,344,210) in view of Bryce-Smith (5,622,724) in further view of Jones et al (6,013,632).

The teachings of Fust and Bryce-Smith have been set forth. Fust teaches a composition for freshening nostrils and sinus cavities that include a saline solution, a flavoring agent, a

preservative, an antiseptic and/or an antimicrobial, a counter-irritant, and an alcohol. Bryce-Smith teaches a zinc sulfate nasal spray for treating the common cold.

The references do not teach the use of N-acetylcysteine.

Jones et al teach N-acetylcysteine nasal spray for the prevention or treatment of infection by the influenza virus (example 24). Jones teaches the N-acetlycysteine is a common mucolytic agent (col. 2, lines 10-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use N-acetylcysteine in Bryce-Smith's nasal spray One would be motivated to do so with a reasonable expectation of success since Bryce-Smith suggests the inclusion of other medicaments such as decongestants in the zinc composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use N-acetylcystine in Fust's composition. One would have been motivated to do so since Jones teaches the common use of N-acetylcysteine as a mucolytic agent. Therefore, one would have been motivated to add an expectorant agent to promote the discharge of mucus from the respiratory tract with a reasonable expectation of success since Fust endeavors to clean the nostrils and the sinus cavities.

Allowable Subject Matter

Claim 12 contains allowable subject matter over the prior art since the prior art does not fairly teach or suggest the instant specific composition that recites specific components with specific weight percents. However, claims 12 are rejected under 35 U.S.C. 112, 1st paragraph, set forth in this Office action and 2nd paragraph. If applicant changes 0.25 camphor to 0.025

camphor, which is supported by the instant specifications and overcomes the second paragraph rejection, the claims would be allowable over the prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG

MICHAEL G. HARTLEY
PRIMARY EXAMINER